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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 11/19/2003 Michael R.S. Hill P-9092-04 7000 10/716,810 EXAMINER 27581 07/11/2005 7590 MEDTRONIC, INC. LAYNO, CARL HERNANDZ 710 MEDTRONIC PARKWAY NE PAPER NUMBER ART UNIT MS-LC340 MINNEAPOLIS, MN 55432-5604 3762

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) |
|---|--|-----------------------|--------------|
| Office Action Summary | | 10/716,810 | HILL ET AL. |
| | | Examiner Carl X. Layo | Art Unit |
| | | Carl H. Layno 7/7/05 | 3762 |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply vill, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 19 November 2003. | | | |
| Status . O | | | |
| 1)🛛 | Responsive to communication(s) filed on 19 No | ovember 2003. | Ö |
| 2a)□ |) This action is FINAL. 2b) This action is non-final. □ | | |
| 3) 🗌 | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merit | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | |
| Disposition of Claims | | | |
| 4) 🛛 | Claim(s) 1-49 is/are pending in the application. | | ੋ |
| | This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merit closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-49 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 21-30 and 36-49 is/are allowed. 6) Claim(s) 1,2,6-8,10,11,13-18 and 31-33 is/are rejected. 7) Claim(s) 3-5,9,12,19,20,34 and 35 is/are objected to. | | |
| 5)⊠ | | | |
| 6)⊠ Claim(s) <u>1,2,6-8,10,11,13-18 and 31-33</u> is/are rejected. 7)⊠ Claim(s) <u>3-5,9,12,19,20,34 and 35</u> is/are objected to. | | | <u> </u> |
| 7)⊠ 8)□ | Claim(s) are subject to restriction and/or | | |
| ordinates) and subject to restriction and/or election requirement. | | | |
| Application Papers | | | |
| 9) The specification is objected to by the Examiner. | | | |
| 10)⊠ The drawing(s) filed on <u>19 November 2003</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner. | | | |
| | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | |
| | | | |
| Priority under 35 U.S.C. § 119 | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some *.c) None of: 1. Certified copies of the priority documents have been received. | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | |
| Attachment(s) | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | |
| 2) Notice 3) Infor | ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) or No(s)/Mail Date: 2/6/04. | Paper No(s)/Mail Da | |

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority filing as a Continuation of U.S Application Serial No. 10/215,443, filed August 9, 2002, now U.S Patent No. 6,690,973, which is a Division of U.S Application Serial No. 09/669,960, filed September 26, 2000, now U.S Patent No. 6,487,446.

Information Disclosure Statement

2. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on February 6, 2004.

Drawings

3. Applicant's formal drawings were received by the Office on November 19, 2003. These drawings are approved by the Examiner.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1, 2, 17, and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mackey '877.

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The Mackey '877 patent describes a method and device for treating acute pain by electrical spinal cord stimulation and drug infusion (col.5, lines 49-51). According to Mackey '877, this pain treatment regimen may be used to treat women in labor and childbirth (col.5, lines 39-42). It would have been obvious, if not inherent, to assume that this pain relief would have been activated prior to and during labor and childbirth to alleviate pain, but turned off afterwords, when no longer necessary.

6. Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Elsberry et al '689.

The Elsberry et al '689 patent describes a method and apparatus (Fig.4) for alleviating cardioversion shock pain. The apparatus 30' includes a processor/microcomputer 62, a spinal cord stimulator (SCS) 120 with attached leads/electrodes 124, and cardiac cardioversion/defibrillation stimulation electrodes 44,46. The spinal cord electrodes 124 are activated only during the detection of a fibrillation S204 (Fig.6) and, hence, are dependent upon the success of the cardiac stimulation electrodes whose outputs provide shock pulses to the patient S214.

In regard to claim 32, the electrodes 124 appear to be wire electrodes since they are shown as being placed adjacent to spinal segments T1 and T4 (Fig.5).

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In regard to claim 33, the cardioversion/defibrillation electrodes 44,46 are considered to be intravascular electrodes since they reside within the superior vena cava 20 and coronary sinus 21, respectively (Fig.4). Alternatively, an epicardial patch electrode may be used (Fig.9).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 8. Claims 6-8, 10, 11, and 13-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6, and 8-11 of U.S. Patent No. 6,487,446. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims reference systems comprising a spinal stimulator, a nerve stimulator, and a cardiac stimulator with the same detailed features.
- 9. Claims 6 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 13 of U.S. Patent No. 6,690,973.

 Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims recite features of a system including a spinal stimulator, a nerve stimulator,

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and a cardiac stimulator (claim 8 of '973) and, additionally, recite similar method steps for delivering a baby involving the starting and stopping of spinal cord stimulation (claim 13 of '973).

Allowable Subject Matter

- 10. Claims 3-5, 9, 12, 19, 20, 34, and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 11. Claims 21-30 and 36-49 are allowed.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (571) 272-4955. All faxed communications should be sent to the Office's Official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (571) 272-4399.

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CARL LAYNO
PRIMARY EXAMINER

CHL 7/7/2005